

Application 10/061,036
Amendment Dated October 2, 2003
Response to Office Action mailed July 2, 2003

REMARKS/ARGUMENTS

In the Office Action mailed July 2, 2003, claim 2 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is respectfully submitted that this rejection is rendered moot by the amendment to claim 2, which deletes "culture media and other clinical and laboratory specimens and samples" from the claim.

In the Office Action, claims 1-19 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being deemed enabling for methods and kits for detecting a target antibody to a mycobacterium utilizing a mycobacterium antigen which binds to said antibody, was deemed to not reasonably provide enablement for detection of an antibody to a particular mycobacterium species utilizing an antigen from any/all other species of mycobacterium. It is respectfully submitted that the amendment to the claims clarifies the invention and that the claims do enable a person of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Independent claim 1, as amended, now claims "A method for detecting the presence of at least one predesignated, target antibody to a Mycobacterium tuberculosis antigen . . ."

Independent claim 11, as amended, now claims "An immunoassay kit for detecting at least one predesignated target mycobacterium antibody to a Mycobacterium tuberculosis antigen . . ."

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In the Office Action, claims 1-19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is respectfully submitted that the amendment to the claims clarifies the invention and that the claims are definite and particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Independent claim 1, as amended, now claims "A method for detecting the presence of at least one predesignated, target antibody to a *Mycobacterium tuberculosis* antigen in a sample selected from one or more patient bodily fluids, which comprises the following steps: (a) contacting the sample with a conjugated label having an indicator dye, thereby forming an antibody-conjugated label complex; (b) allowing the antibody-conjugated label complex to migrate along a lateral-flow assay membrane and contact at least one membrane-bound *Mycobacterium tuberculosis* antigen, thereby forming an antigen-antibody complex and causing the indicator dye to precipitate and form a detectable signal; and (c) detecting the signal, whereby the presence of the target antibody is determined in the sample by the presence of the signal."

As claimed, a detectable signal is formed only when an antigen-antibody complex is formed, *i.e.*, the antibody is present to form that complex with the antigen.

Similarly, independent claim 11, as amended, now claims "An immunoassay kit for detecting at least one predesignated target antibody to a *Mycobacterium tuberculosis* antigen in a sample selected from one or more patient bodily fluids which comprises: (a) a sample pad, (b) a conjugated label pad, the conjugated label pad having an indicator

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dye, a portion of the conjugated label pad and a portion of the sample pad forming a first interface, (c) a lateral-flow assay comprising a membrane, a portion of the membrane and a portion of the conjugated label pad forming a second interface, and (d) at least one *Mycobacterium tuberculosis* antigen bound to the membrane, the first interface allowing fluid to flow from the sample pad to the conjugated label pad and contact the indicator dye wherein the predesignated target antibody present in the sample forms a first complex with the conjugated label, the second interface allowing fluid to flow from the conjugated label pad to the membrane and to contact the at least one *Mycobacterium tuberculosis* antigen, the antigen forming a complex with the predesignated target antibody present in the sample and causing the indicator dye to precipitate and form a detectable signal."

In the Office Action, claim 5 was objected to because of an informality. Claim 5 has been clarified by amendment and now claims "*Mycobacterium tuberculosis*".

In the Office Action, claim 6 was objected to because of an informality. Claim 6 has been clarified by amendment and now claims "of" between the words "mixture" and "two".

Concurrently submitted with this Response is a Supplemental Information Disclosure Statement. It is respectfully submitted that the pending claims are patentable over the cited art. None of the cited art teaches or suggests the claimed invention as set forth in independent claims 1 and 11, or the pending dependent claims 2-10, and 12-29.

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Conclusion

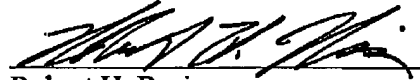
In view of the foregoing, it is respectfully submitted that the pending claims 1-29 are in condition for allowance. Favorable action is earnestly solicited.

Respectfully submitted

Banner & Witcoff, Ltd.

Date: October 2, 2003

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